UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. HEC PHARM CO., LTD., HEC PHARM USA, MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN LABORATORIES LIMITED, ACCORD HEALTHCARE, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., ZYDUS PHARMACEUTICALS USA, INC., CADILA HEALTHCARE LTD., MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., PRINSTON PHARMACEUTICAL INC., INVAGEN PHARMACEUTICALS INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL FZE, TEVA PHARMACEUTICALS USA, INC., Defendants.	Civil Action No. 3:15-cv-5982-PGS-TJB (consolidated with Civil Action Nos. 3:16-cv-00852-PGS-TJB, 3:16-cv-00851-PGS-TJB, and 3:16-cv-02394-PGS-TJB) BRIEF IN SUPPORT OF RULE 12(c) MOTION TO DISMISS THE CLAIMS OF INFRINGEMENT OF U.S. PATENT NO. 8,853,156

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INTRODUCTION

The defendants alleged to infringe U.S. Patent No. 8,853,156 ("the '156 patent") bring this motion to dismiss pursuant to Federal Rule of Civil Procedure 12(c), because the claims of the '156 patent do not recite patent-eligible subject matter and are therefore invalid under 35 U.S.C. § 101.[1] Simply put, the claims of the '156 patent recite nothing more than a natural law based on pharmacokinetic observations of diabetic patients. The Supreme Court has recently rejected just such claims as an improper effort to claim natural laws and thereby preempt further exploration and scientific development. *Mayo v. Prometheus Labs.*, 132 S. Ct. 1289 (2012); *see also Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

The '156 patent asserts that the inventors "discovered" the fact that the antidiabetic drug linagliptin and other antidiabetic drugs of the same class known as "DPP-4 inhibitors" are metabolized primarily through the liver rather than the eliminated through the kidney and therefore can be safely used in patients with renal (*i.e.* kidney) insufficiency. Based on this purported discovery, the '156 patent claims the use of linagliptin and other DPP-4 inhibitors when metformin, another antidiabetic drug of a different class that is eliminated by the kidney, cannot be used. The patent explains that it has long been known that metformin should generally not be used in patients with renal insufficiency. In other words, Plaintiffs supposedly identified that linagliptin and similar drugs were safe for use in patients with renal insufficiency, then identified a second drug known not be safe for use in patients with renal insufficiency, and claimed the idea that the former drugs could be used when the latter could not.

[1] The movants ("Defendants") include all defendants except Invagen Pharmaceuticals Inc., which was not sued on the '156 patent.

Regardless of how the supposed invention is phrased, however, the patent claims do nothing more than claim a natural law, which is ineligible subject matter under § 101. Specifically, the claims recite pharmacokinetic properties associated with renal safety, and the remaining limitations do nothing more than recite conventional, routine, and well-understood activities associated with administering oral antidiabetics. The claims therefore cannot survive scrutiny under § 101.

Furthermore, the supposed "discovery" that linagliptin and related drugs can be used in patients with renal impairment is not even a "discovery" at all, because as will be discussed, the prior art incorporated by reference into in the '156 patent specification makes clear that DPP-4 inhibitors were already known to be useful in patients with renal impairment. Thus, at best the inventors merely discovered pharmacokinetic and metabolic properties that explain *why* these compounds were useful in such patients. The "discovery" of an inherent consequence of a previously known method does not render the method patentable.

Thus, the '156 patent is nothing more than an attempt to inappropriately preempt others from using linagliptin and other drugs of the same class well beyond the expiration of compound patent claiming linagliptin. As the Supreme Court explained in *Mayo v. Prometheus*, this is exactly the sort of activity that the patent-eligibility doctrine of § 101 seeks to prevent. The Court should dismiss the '156 patent from the case.[2]

BACKGROUND

This is a consolidated Hatch-Waxman case involving Plaintiffs ("Boehringer"), eleven different defendant groups, eleven different "Orange Book" patents, and two different products.

[2] As detailed below, the Court should consider Defendants' Rule 12(c) motion on the merits irrespective of whether it grants Defendants leave to amend their invalidity contentions which only upon amendment will contain a § 101 defense.

The various defendants have filed abbreviated new drug applications seeking approval to market generic versions of Boehringer's antidiabetic drugs Tradjenta (linagliptin) and/or Jentadueto (combination linagliptin and metformin). Boehringer has sued each defendant on various Orange Book patents, depending upon which patents each defendant challenged and upon which product or products each defendant seeks to market. Only the '156 patent, which claims methods of treatment, is at issue here. With a listed expiration date of March 5, 2031, the '156 patent is the last to expire of the Orange Book patents. The patent's expiration date is nearly six years beyond the May 2, 2025 expiration of the patent claiming the linagliptin compound itself, U.S. Patent No. 7,407,955.

The '156 patent is entitled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy." As noted, the patent concerns a class of antidiabetic drugs known as "DPP-4 inhibitors," to which linagliptin belongs. The patent explains that "[t]he present invention relates to the finding that certain DPP-4 inhibitors are particularly suitable for treating and/or preventing metabolic diseases, particularly diabetes, in patients for whom metformin therapy is inappropriate due to intolerability or contraindication against metformin." Ex. 1 at Abstract.[3] Boehringer asserts infringement of claims 10-17 and 24-25 against Defendants.[4] The former group of claims depends from claim 1; claim 11 is illustrative:

> 1. A method of treating and/or preventing metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient a DPP-IV inhibitor wherein the contraindication is selected from the group consisting of:

[3] "Ex." refers to exhibits attached to the supporting declaration of Philip L. Hirschhorn.

[4] Boehringer narrowed its asserted claims after the pleadings were closed and this brief focuses on the asserted claims because they are presently the only ones at issue in the case. However, to the extent all of the claims must be addressed because this motion is limited to material in the pleadings, the remaining claims are discussed in footnote 7.

> renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance.
>
> 11. The method according to claim 1, characterized in that said DPP-4 inhibitor and its major active metabolite(s) are primarily eliminated via hepatic metabolism or biliary excretion.

Ex. 1 at 29:1-11; 31:61-64. The primary "discovery" behind claim 11 is that certain DPP-4 inhibitors are metabolized primarily by the liver rather than being eliminated primarily by the kidney and that therefore, those DPP-4 inhibitors can be used when metformin cannot. Similarly, claims 24 and 25 are independent claims that specifically recite the treatment of type 2 diabetes (instead of "metabolic diseases") and the use of linagliptin (instead of "a DPP-4 inhibitor"). Claim 25 is narrower and merely recites:

> 25. A method of treating [type] 2 diabetes mellitus in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient [linagliptin], wherein the contraindication is selected from the group consisting of mild, moderate or severe renal impairment or end-stage renal disease.

Ex. 1 at 32:57-64.

The specification of the '156 patent discloses that aside from the recitation of a natural law concerning the pharmacokinetics of linagliptin in comparison to metformin, the remaining claim limitations are routine and conventional. As discussed below, the specification discloses that renal impairment was known to be common in diabetics, that metformin was a known antidiabetic agent known to be contraindicated in patients with renal impairment, and that linagliptin was known to be useful in diabetics with renal impairment. Thus, the remaining limitations add no inventive significance to the recited pharmacologic properties.

ARGUMENT

I. The Court Should Dismiss the Asserted Claims of the '156 Patent Because They Recite Patent-Ineligible Subject Matter and Nothing More.

A. The Court may dismiss the asserted claims based on the specification of the '156 patent because the patent-eligibility of the asserted claims presents an issue of law.

Rule 12(c) provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." "The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference." *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F.Supp.2d 612, 617 (D.Del.2008).

The ultimate question of patent eligibility is an issue of law, making it an appropriate basis for a Rule 12(c) motion. *See In re Bilski*, 545 F.3d 943, 951 (Fed.Cir.2008), *aff'd,* 561 U.S. 593 (2010). The Federal Circuit has held that § 101 challenges are appropriate bases for a motion for judgment on the pleadings. *See, e.g., OIP Techs., Inc. v. Amazon.com, Inc.,* 788 F.3d 1359, 1360 (Fed. Cir. 2015); *buySAFE, Inc. v. Google, Inc.,* 765 F.3d 1350, 1355 (Fed. Cir. 2014). In this instance, all of the information needed to decide this motion is present in the '156 patent specification (which the complaint incorporates by reference), or the materials referenced therein (public documents which the patent expressly incorporates by reference). Accordingly, the Court can dismiss the '156 patent from the case without further discovery or proceedings.[5]

B. Section 101 of the patent code prohibits patenting laws of nature.

Section 101 of the Patent Act defines patentable subject matter:

[5] Boehringer will likely assert that judgment on the pleadings is not proper because certain '156 patent claim terms are disputed and the Court has not yet issued a claim construction ruling. To the contrary, there are no disputed claim terms relevant to this motion.

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101. The Supreme Court has long held that this provision contains important exceptions: "laws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond v. Diehr,* 450 U.S. 175, 185 (1981). In other words, "[p]henomena of nature, though just discovered . . . are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk v. Benson,* 409 U.S. 63, 67 (1972).

The Supreme Court's *Alice* and *Mayo* decisions set forth a two-step framework for determining whether a claim is patent-eligible under § 101. *Alice,* 134 S. Ct. at 2355; *Mayo,* 132 S. Ct. 1296-97. The first step is to determine whether the claims at issue are directed to a patent-ineligible concept, *i.e.*, a law of nature, natural phenomenon, or abstract idea. *Alice*, 134 S. Ct. at 2355; *see also Mayo*, 132 S. Ct. at 1296-97. The second step, invoked when a claim embraces patent-ineligible subject matter, is to "search for an 'inventive concept'—*i.e.*, an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.'" *Alice*, 134 S. Ct. at 2355 (citation and brackets omitted); *see also Mayo*, 132 S. Ct. at 1297. As explained by the Court in *Mayo*, the relevant question is "do the patent claims add *enough* to their statements of [natural laws] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" *Id*. (emphases in original).

The reason for the second step is to prevent clever draftsmanship from dressing up claims that recite nothing more than one of these exceptions with claim language of little actual substance. The Court in *Mayo* explained that patent eligibility should not "depend simply on the draftsman's art" and be nothing more than "a drafting effort designed to monopolize the law of

nature itself." *Id*. at 1294, 1297 (internal quotations omitted). Accordingly, if the claim limitations are directed toward a natural law or phenomenon but then merely add "well-understood, routine, conventional activity previously engaged in by scientists who work in the field[,]" this does not make such a claim patent eligible, because adding "[p]urely conventional or obvious pre-solution activity is not normally sufficient to transform an unpatentable law of nature into a patent eligible application of such a law." *Id*. at 1298 (internal quotations and brackets omitted); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371, 1378 (Fed. Cir. 2015) ("Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine, and well understood applications in the art"), *cert. denied,* 84 U.S.L.W. 3548 (U.S. Jun. 27, 2016) (No. 15-1182).

Applying this two-step framework, both the Supreme Court in *Mayo* and recently, the District of Delaware, have found claims similar to the ones asserted here invalid under § 101. *See Mayo*, 132 S. Ct. at 1297-98; *Endo Pharms. Inc. v. Actavis Inc.,* No. 14-1381, 2015 WL 7253674 (D. Del. Nov. 17, 2015).

In *Mayo*, the method claimed did nothing more than state a natural law governing the effects of certain types of drugs (thiopurine compounds) on the body for the treatment of autoimmune diseases (such as Crohn's disease), along with routine and conventional treatment steps provided by a physician (*i.e.,* determining whether a given dosage level is too low or too high). *See Mayo*, 132 S. Ct. at 1294. At the time the discoveries in the patent were made, scientists already understood that the levels of certain thiopurine metabolites in a patient's blood known as "6-TG" and "6-MMP" were correlated with the likelihood that a particular dosage of a thiopurine drug would be effective or could cause toxicity. *Id.* at 1295. The "discovery" was the

particular correlation, *i.e.,* that "concentrations in a patient's blood of 6-TG or of 6-MMP metabolite beyond a certain level (400 and 7000 picomoles per $8x10^8$ red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations in the blood of 6-TG metabolite lower than a certain level (about 230 picomoles per $8x10^8$ red blood cells) indicate that the dosage is likely too low to be effective." *Id.* at 1295. The *Mayo* patent consequently claimed "[a] method of optimizing therapeutic efficacy for treatment" of an immune disorder comprising the steps of administering the drug to patients with the disorder and determining the level of 6-TG in the patient, "wherein" the level of 6-TG higher than recited above indicated a need to decrease the thiopurine dose and a level of 6-TG less than recited above indicated a need to increase the thiopurine dose. *Id.*

In analyzing the claims in *Mayo*, the Supreme Court observed that the patent claimed a law of nature, "namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." 132 S. Ct. at 1296. The Court explained that such relationships are natural laws because they are "a consequence of the ways in which [drugs] are metabolized by the body -- entirely natural processes." *Id.* at 1297.

Turning to the second step, the Court explained that to be patent eligible the claims would have to add enough to the law of nature to qualify as a patent eligible process that applies a natural law in an inventive way. *Id.* The Court then held that the additional steps in *Mayo* did not do that. The "administering" step did nothing more than limit the relevant audience to "doctors who treat patients with certain diseases with thiopurine drugs." *Id.* at 1297. Merely limiting a natural law to a particular technological environment did not render the claim patent-eligible. *Id.* Similarly, the "determining" step merely told the doctor to determine the level of the relevant

metabolites in the blood. *Id.* Because such methods were well-known in the art, the "determining" step was considered conventional "pre-solution activity" that did not apply the law of nature in a way to create a patent-eligible process. *Id.* at 1298. Finally, the "wherein" clauses simply told the doctor what the relevant natural laws were, at most suggesting that doctors take the laws of nature into account when treating patients. *Id.* at 1297.

Following *Mayo*, the district court in Delaware granted a motion to dismiss and rejected patent claims similar to those at issue here. *Endo Pharms. Inc. v. Actavis Inc.,* No. 14-1381, 2015 WL 7253674 (D. Del. Nov. 17, 2015), *adopting Mag. Report and Recommendations in Endo Pharms. Inc. v. Actavis Inc.,* No. 14-1381, 2015 WL 5580488 (D. Del. Sep. 23, 2015). The central "discovery" in the *Endo* patent was that "the bioavailability of controlled released oxymorphone [a pain medication] is affected by renal [kidney] function or that renally impaired patients could or should be treated safely and effectively by administering to them a reduced dosage" of oxymorphone. *Endo*, 2015 WL 7253674, at *1 (internal quotations omitted). The claims were directed to a method of treating pain in "a renally impaired patient" by providing a certain dosage of the controlled release drug, measuring renal impairment by creatinine clearance, and administering a lower dosage according to the results of the testing. *See Endo*, 2015 WL 5580488, at *1 - *2, *7; *see also Endo*, 2015 WL 7253674, at *2.

Applying the two step *Mayo* framework, the court ruled that the claims were facially invalid under § 101. First, the court ruled that the recognition that lower doses must be used for patients with renal impairment was merely directed to a natural law. *See Endo*, 2015 WL 7253674, at *2 - *3 ("noting that that the subject matter of the invention was "the connection between the severity of renal impairment and the bioavailability of oxymorphone"); *see also* 2015 WL 558048, at *6. Second, the court concluded that the remaining steps in the claim, *i.e.,*

"providing" the drug, measuring/determining renal function, and "administering" the correct dosage were similar to the well-understood, conventional, and routine activities in *Mayo*. *See* 2015 WL 5580488, at *8.

C. The claims of the '156 patent are invalid under § 101 for the same reasons discussed in *Mayo* and *Endo*.

Just as in *Mayo* and *Endo*, the asserted claims of the '156 patent are directed to laws of nature and add nothing to those laws beyond well-understood, routine, conventional activity.

1. The asserted claims are directed to laws of nature.

The asserted claims of the '156 patent are directed to laws of nature because, like *Mayo* and *Endo*, they essentially recite pharmacokinetic or metabolic properties of pharmaceutical compounds -- here, certain DPP-4 inhibitors including linagliptin. Claims 10-17, for example, are directed to a method of treating metabolic diseases in "a patient for whom metformin therapy is inappropriate" comprising orally administering to the patient a DPP-4 inhibitor.[6] The patent's specification first notes that metformin is an antidiabetic drug that is used alone or in combination with other antidiabetics, is "largely eliminated unchanged by the kidney" and is therefore "contraindicated in patients with renal disease or renal impairment." Ex. 1, at 50-55; 1:62-65. The patent later explains that the invention relates to the "finding" that certain DPP-4 inhibitors are particularly suitable for treating metabolic diseases because they have "particularly advantageous properties" that make them useful when metformin cannot be used:

> it has now surprisingly been found that DPP-4 inhibitors as defined herein have surprising and particularly advantageous properties, which make them particularly suitable for treating and/or preventing (including preventing or slowing the progression) of metabolic diseases, particularly diabetes (especially type 2

[6] Claims 10-17 depend from claim 1 and thereby include these limitations. Claims 24 and 25 are similar. As noted earlier, they simply narrow this method to the treatment of type 2 diabetes specifically and the use of linagliptin specifically.

> diabetes mellitus) and conditions related thereto (e.g. diabetic complications), particularly in patients for whom metformin therapy is inappropriate due to intolerability or contraindication against metformin, such as patients ineligible for metformin therapy or patients in need of metformin dose reduction due to intolerability or contraindication against metformin.

Ex. 1 at 9:30-41. The patent identifies these "particularly advantageous properties" when it explains that "[a] DPP-4 inhibitor which may be suggested for the purpose of the present invention (especially for patients with impaired renal function) . . . [is one] primarily eliminated via hepatic metabolism or biliary excretion." *Id.* At 13: 29-36. In other words, as a result of the "discovery" of the allegedly surprising property that some DPP-4 inhibitors are metabolized by the liver (rather than the kidney, as is metformin), the present invention provides a DPP-4 inhibitor for use where metformin use is inappropriate "in more particular in patients with renal disease, renal dysfunction or renal impairment [] characterized in that said DPP-4 inhibitor is excreted substantially or mainly via the liver[.]." *Id.* at 14: 41-48. According to the specification, other properties that make certain DPP-4 inhibitors "particularly suitable" for the invention include having a "relatively wide (*e.g.*, > 100 fold) therapeutic window and/or [fulfilling] one or more of the following pharmacokinetic properties[:]" (a) "substantially or mainly excreted via the liver . . . and/or for which renal excretion represents no substantial or only a minor elimination pathway[;]" (b) "excreted mainly unchanged as parent drug[;]" and (c) "[t]he (main) metabolite(s) . . . is/are pharmacologically inactive." *Id.* 13:29-61.

The foregoing pharmacokinetic and/or metabolic properties are the very properties recited in the claims. For example, claim 11 recites a method of treatment comprising the administration of a DDP-4 inhibitor to a patient for whom metformin is contraindicated "characterized in that said DPP-4 inhibitor and its major active metabolite(s) are primarily eliminated via hepatic metabolism or biliary excretion." *Id.* at 29:1-14 and 31:61-64. The

remaining claims likewise recite similar properties or the consequences of having these properties.[7] All of these claims are directed to pharmacokinetic properties of certain DPP-4 inhibitors (especially linagliptin), and/or to the relationship between these properties and the fact that these drugs can be used when metformin cannot be used because of renal insufficiency. Like the discovery of the relationship between blood levels and toxicity in *Mayo*, the "discovery" of giving diabetics with renal impairment a compound metabolized by the liver instead of a compound contraindicated in diabetics with renal impairment is "a consequence of the ways in which [drugs] are metabolized by the body-- entirely natural processes." *Mayo*, 132 S. Ct. at 1297. Similarly, the relationship between the pharmacokinetic properties of the DPP-4 inhibitors recited in the '156 patent and renal impairment, and the fact that such drugs can be used in renally impaired patients who consequently cannot use metformin, is akin to the "discovery" in *Endo* that "the bioavailability of controlled released oxymorphone is affected by renal function"

[7] Claim 12 recites "wherein said DPP-4 inhibitor is excreted mainly via the liver." Claim 13 recites "for which excretion via the kidney represents a minor elimination pathway." Claim 14 recites "wherein said DPP-4 inhibitor is excreted mainly unchanged." Claim 15 recites "for which elimination via metabolism represents a minor elimination pathway." Claim 16 recites "wherein said DPP-4 inhibitor has placebo-like safety/tolerability and/or is eliminated primarily as the parent drug via the liver." Claim 17 recites "wherein the main metabolite of said DPP-4 inhibitor is pharmacologically inactive." The other claims merely recite the consequence of these properties, namely that "said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function" (claim 10) or that the contraindication for metformin is selected from a group including "renal disease" (claims 24 and 25).

The unasserted claims of the '156 patent do not substantively differ because they all embody the discovery of the same natural law or relationship. All but one of the remaining unasserted claims depend from claim 1 and merely recite the contraindications or diseases we have been discussing (claims 2, 4, 5, and 18), recite that a "reduced dose" of metformin is needed because of the contraindication (claim 3), specify certain DPP-4 inhibitors (claims 6-9), or recite that the DPP-4 inhibitor is used in combination therapy (claims 19-22). Claim 23 is an independent claim similar to claims 24 and 25 except that it broadly recites the use of DPP-4 inhibitors instead of linagliptin.

and that "renally impaired patients could or should be treated safely and effectively by administering to them a reduced dosage" of oxymorphone. *Endo*, 2015 WL 7253674, at *1 (internal quotations omitted). Therefore just as in *Mayo* and *Endo*, the '156 patent claims are directed to natural laws.

Boehringer will likely argue that the claims at issue are not directed to a natural law, but instead to a new and useful process based on discovery of a natural law. In particular, based on a recent pleading here, Boehringer may inappropriately try to shoehorn the Federal Circuit's recent decision in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.,* No. 2015-1570, 2016 WL 3606624 (Fed. Cir. Jul. 5, 2016) to fit the facts in this case. In that pleading, Boehringer argued that Defendants' motion to amend its contentions based on Section 101 was "futile" because *Rapid Litigation Management* held that "methods of treatment claims, which are at issue in the instant motion, are patentable subject matter." Docket No. 325 at 16. Boehringer misstates the holding in *Rapid Litigation Management.* The court did not establish a *per se* rule that "methods of treatment claims" are patentable subject matter – nor could it, because that would be inconsistent with *Mayo*, which involved methods of treatment. In fact, the court in *Rapid Litigation Management* was not even dealing with a method of treatment – rather, the claims recited methods of producing hepatocytes (liver cells) primarily for use in biomedical research applications. *See* 2016 WL 3606624, at *2 - *4. Furthermore, the actual steps of the methods recited in *Rapid Litigation Management* had not been previously performed. *See id.* at *3 - *4 (noting that the claims were directed to a "new and improved way of preserving hepatocyte cells for later use"). That is the opposite of this case where, as discussed below, all of the recited steps in the claims were previously known and performed.

Rapid Litigation Management further distinguished *Mayo* and *Alice* on the grounds that the claims in those cases were directed to "nothing more than observing or identifying the ineligible concept itself." *See id.* at *4. As discussed above, that is precisely what the '156 patent claims do – they are merely directed to "observing or identifying" the pharmacokinetic and metabolic properties of known compounds, which is not patent eligible. Clever draftsmanship cannot change this fact. The Supreme Court's decisions in *Mayo* and *Alice*, not the Federal Circuit's reasoning in *Rapid Litigation Management,* apply here.

Moreover, a similar argument was squarely rejected by the *Endo* court under circumstances similar to those here. There, the patentees argued that the invention was not directed to a natural law, but rather "to a new and useful process (the altered treatment regimen) that provides a practical, tangible benefit (relief of pain) in a particular population." *Endo*, 2015 WL 7253674, at *1; *see also* 2015 WL 558048 at *6. The court noted, however, that the specification explained that oxymorphone was widely used to treat pain, so the utilization of oxymorphone was not the invention. *Endo*, 2015 WL7253674, at *3; *see also Endo*, 2015 WL 558048, at *6. Similarly, the '156 patent specification makes clear that it was well-known that DPP-4 inhibitors were used to treat diabetes because it cites numerous patent publications illustrating this fact, *see, e.g.,* 4:15 – 9:26, and expressly incorporates those publications by reference, *id.* at 9:27-29.[8] Furthermore, the specification acknowledges the specific DDP-4 inhibitor linagliptin itself was known to be useful for the treatment of diabetes. *See, e.g.,* 4:16-17

[8] S*ee also In re Burlington Coat Factory Sec. Litig.,*114 F.3d 1410, 1426 (3d Cir.1997) (explaining that any documents integral to pleadings may be considered in connection with Rule 12(c) motion). Thus, the Court "may consider matters of public record as well as authentic documents upon which the complaint is based if attached to the complaint or as an exhibit to the motion." *Inventor Holdings, LLC v. Gameloft, Inc.,* 135 F. Supp. 3d 239, 244 (D. Del. 2015); *see also Oshiver v. Levin,Fishbein, Sedran & Berman,* 38 F.3d 1380, 1384 n.2 (3d Cir. 1994).

(citing WO 2004/018468).[9] Thus, as in *Endo*, the utilization of DPP-4 inhibitors or linagliptin is not the invention – rather, it is the pharmacokinetic or metabolic properties to which the claims are directed. These are unquestionably laws of nature and are not patent-eligible.

2. There is no additional inventive concept sufficient to ensure the claims amount to significantly more than a patent upon the natural law itself.

Because the claims are directed to natural laws, the second question is whether the asserted claims add enough to transform them from an unpatentable law of nature into a patent-eligible application of that law. They do not. Broadly speaking, in addition to the natural laws recited above, the claims recite: (1) administering a DPP-4 inhibitor (claims 10-17) or, more specifically, linagliptin (claims 24-25); (2) for the treatment or prevention of diabetes mellitus. However, these limitations -- alone or in combination-- all merely describe well-understood, routine, conventional, and obvious activity. The '156 patent specification acknowledges that it was well known that DPP-4 inhibitors could be used to treat diabetes because it cites numerous patent publications illustrating this fact, *see, e.g.,* 4:15 – 9:26 (citing sitagliptin, vildagliptin, saxagliptin, alogliptin, and others), and expressly incorporates those publications by reference, *id.* at 9:27-29. Furthermore, the specification acknowledges linagliptin itself was known to be

[9] The specification states that "DDP-4 inhibitors and their uses, particularly their uses in metabolic (especially diabetic) diseases, are disclosed in" a number of publications, including WO 2004/018468. Ex. 1 at 4:15-18. The specification further notes that "[f]or avoidance of any doubt, the disclosure of each of the foregoing documents cited above is specifically incorporated by reference in its entirety." Ex. 1 at 9:27-29.

Portions of WO 2004/018468 and a corresponding English document (Canadian Patent Application or CA 2496249) are marked as Exs. 2 and 3, respectively. These documents identify linagliptin as compound 2(142), *see* Ex. 2 at 165; Ex. 3 at 161, and explain that linagliptin and related DPP-4 inhibitors are useful in the treatment of diabetes. *See* Ex. 2 at 1, 36; Ex. 3 at 1, 35. Linagliptin is specifically claimed. *See* Ex. 2 at 221; Ex. 3 at 213; *compare with* Ex. 1 at 32:48-60 (claims 24-25).

useful for the treatment of diabetes. *See, e.g.,* 4:16-17 (citing WO 2004/018468). Thus, there is nothing inventive in these additional limitations or in their combination.[10]

Defendants have already pointed out that administering DPP-4 inhibitors to treat diabetes "under circumstances where metformin is inappropriate" is just a restatement of a natural law because it merely describes the relationship between observed pharmacokinetic properties and when DPP-4 inhibitors can be used. But to the extent this phrase could be considered a separate, additional limitation beyond the discovery itself, it similarly does not involve anything inventive alone or in combination with the other limitations. That is because everything explicitly or implicitly described in this phrase was in the prior art. In addition to acknowledging that DPP-4 inhibitors such as linagliptin were used to treat diabetes, the specification also acknowledges that metformin was a known diabetes treatment, *see* Ex. 1 at 1:51-55, and that metformin was contraindicated in patients with renal disease, renal impairment, or conditions thought to be associated with renal impairment such as lactic acidosis, *see id.* at 55-68. The specification also makes clear that nephropathy, renal impairment, and renal failure are well-known complications of diabetes. *See* Ex. 1 at 1:17-25.[11] Furthermore, the means by which to measure renal function and determine if a patient had renal impairment was also well-known. *See id*. at 3:1-48. Under similar circumstances the *Endo* court concluded that there was no "inventive leap" in the disputed patent because it merely claimed a reduced dose of a "well-known method of treating pain" and "merely tells doctors to apply the natural law." *Endo*, 2015 WL 7253674, at *4; *see*

[10] The unasserted claims do not add anything different other than combination therapy. *See* note 7 *supra*. Combination therapy for diabetes was also well-known, routine, and conventional. *See, e.g.,* Ex. 1 at 1:51-55; 4:59-62; 5: 28-31; 6:25-27; 8:58-59; 12:24-26; 25:1-31.

[11] Nephropathy is "[o]ne of the typical long-term complications of diabetes" and can progress to renal failure. Ex. 1 at 1:23-25.

also Mayo, 132 S.Ct. at 1294 ("one must do more than simply state the law of nature while [effectively] adding the words 'apply it'"). The same can be said here -- Boehringer "discovered" that a drug that is safe to use in renal impairment can be used in place of one that is not. There is nothing inventive in this additional limitation or in combining it with other limitations.

The conclusion that there is nothing inventive in these claims is further emphasized by the fact that the '156 patent specification makes clear that the use of DPP-4 inhibitors to treat diabetics with renal insufficiency was actually previously known. As noted, the specification expressly incorporates a number of other publications in their entirety. *See* Ex. 1 at 9:27-29. These include WO2006/135723[12] (Ex. 4), which expressly notes that a composition of vildagliptin (another DPP-4 inhibitor) may be used to treat diabetes as well as diabetic complications such as nephropathy and other renal diseases. *See, e.g.,* Ex. 4 at p.21:11-19; p.40: 33 – p.41: 8; p.50: 9 – p. 51:16; p.127:16 – p.128: 24. Other examples include WO 2003/004498[13] (Ex. 5), which also instructs that DPP-4 inhibitors can be used to treat nephropathy associated with diabetes, *see* Ex. 5 at p.13:34 – p.14:10; p.62:23 – p. 64:3, and WO 2007/050485[14] (Ex. 6), which similarly instructs that DPP-4 inhibitors can be used in patients with nephropathy, *see* Ex. 6 at p.3:25 – p.4:4.

Considering the foregoing, it was known that: (1) DPP-4 inhibitors and linagliptin could be used to treat or prevent diabetes; (2) nephropathy and renal impairment was common in diabetics; (3) DPP-4 inhibitors could be used to treat diabetics with nephropathy and renal impairment; (4) metformin was used to treat diabetes; and (5) metformin was contraindicated

[12] *See* Ex. 1 at 5:22-23.

[13] *See* Ex. 1 at 4:51-54.

[14] *See* Ex. 1 at 4:55.

with renal impairment. Therefore, application of the supposed "discovery" that DPP-4 inhibitors (or certain DPP-4 inhibitors including linagliptin) could be used to treat diabetes in those with renal impairment involves nothing more than well-understood, routine, conventional, and obvious activity. As in *Mayo*, the "administering" step merely refers to the relevant audience, *e.g.*, physicians who treat diabetics. *Mayo*, 132 S.Ct. at 1297. And as in *Mayo*, the remaining steps (to the extent there are any) merely instruct physicians to engage in conventional activity by "determining" whether a patient has renal insufficiency and then if so, administering a DPP-4 inhibitor generally or linagliptin specifically. *Id.* at 1297-98. As in *Endo,* providing the drug, measuring and/or determining renal function, and administering the correct dosage are routine. *See Endo*, 2015 WL 5580488, at *8. Nor is there anything inventive in the ordered combination of any of these activities. "Administering" a DPP-4 inhibitor to certain patients (those with renal insufficiency) to treat diabetes "amounts to nothing significantly more than an instruction to doctors to apply the applicable [natural] laws when treating their patients." *Mayo*, 132 S.Ct. at 1298.

In short, there is nothing inventive in giving a known antidiabetic drug previously described as useful for diabetic patients with renal impairment to diabetic patients who cannot tolerate another known antidiabetic drug because they have predictable renal impairment, on the basis of the supposed later "discovery" that the former drug does not cause renal impairment. If anything, the inventors' "discovery" was nothing more than the recognition of particular inherent pharmacokinetic or metabolic properties that explain why certain DPP-4 inhibitors do not cause renal impairment. This is clearly not patentable. *See, e.g., Eli Lilly & Co. v. Barr Labs.,* 251 F.3d 955, 971 (Fed. Cir. 2001) (rejecting a claim which "simply describes the process by which

fluoxetine hydrochloride physically acts on individuals who receive the drug"). Neither the discovery nor the methods claimed are patent-eligible under § 101.

D. The policy behind the Supreme Court's *Mayo* decision applies here.

The policy underlying the Supreme Court's *Mayo* decision is the same policy that has driven the Court's § 101 jurisprudence for more than a century: "a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." *See Mayo,* 132 S. Ct. at 1301. The Court noted that its precedents "warn us against upholding patents that claim processes that too broadly preempt the use of a natural law" because such laws are "the basic tools of scientific and technological work." *See id.* at 1294, 1301 (internal quotations omitted). Even though the methods claimed in *Mayo* were narrow, the Court reasoned that they inappropriately "tie[d] up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference" drawn by using the natural law. *Id.* at 1302. The claims further inappropriately "threaten[ed] to inhibit the development of more refined treatment recommendations" based on later discovered features of metabolites. *Id.*

The same holds true here. The patent, if upheld, preempts conventional medical practice: treating diabetic patients with renal impairment with a type of drug known to be safe for patients with renal impairment. Notably, claims 10-17 "threaten to inhibit the development of more refined treatment" by preempting the use of *any* DPP-4 inhibitor for *any* metabolic disease whose pharmacokinetic properties render it safe to use with renal disease. Similarly claims 24-25 of the '156 patent attempt to preempt the use of linagliptin for diabetes, well beyond the expiration of the compound patent claiming linagliptin, based on clever claim draftsmanship derived from the recognition of a natural law. The Court in *Mayo* recognized the problem, raised by *amici* including the American Medical Association, the American Hospital Association, and

other medical organizations, that if "claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." 132 S. Ct. at 1304 (internal citation and quotations omitted). So too would be the result here, should the use of observed pharmacokinetic parameters in the '156 patent or safety based on those parameters be allowed to stand.

II. The Court Should Consider Defendants' Rule 12(c) Motion on the Merits Irrespective of its Decision Whether to Grant Defendants Leave to Amend.

Defendants did not include this § 101 defense in their preliminary invalidity defenses for the '156 patent, and recently sought Boehringer's consent to amend in order to include it. Boehringer refused. Because Boehringer refused to consent, Defendants have sought leave to amend their contentions to include this argument. *See* Docket No. 321. Defendants suspect Boehringer may argue that this Rule 12(c) motion is untimely or otherwise contingent on the outcome of the Court's consideration of Defendants' request for leave to amend. However, the two motions are distinct and should not be conflated. For the reasons discussed below, the Court should consider Defendants' Rule 12(c) motion on the merits irrespective of whether it grants Defendants leave to amend, because to fail to consider Defendants' Rule 12(c) motion under these circumstances would elevate the form of local rules over substance and would be inconsistent with the Federal Rules.[15]

As previously noted, Rule 12(c) provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." The "obvious

[15] Of course, if the Court grants Defendants' motion for leave to amend, this Section II of Defendants' brief is moot.

purpose" of the rule "is to save time and expense in cases wherein the ultimate facts are not in dispute." *Wise v. Washington Cnty.,* No. 10-1677, 2015 WL 1757730, at *22 (W.D. Pa. Apr. 17, 2015); *see also Ulen Contracting Corp. v. Tri-County Elec. Co-op.,* 1. F.R.D. 284, 285 (W.D. Mich. 1940). The standard for evaluating a Rule 12(c) motion is the same as the standard for evaluating a Rule 12(b)(6) motion. *Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *Hoch v. Phelan,* 796 F. Supp. 130, 132 (D.N.J. 1992). The only difference is that the pleadings are closed in the former, whereas they have not been closed in the latter. *See Hoch,* 796 F. Supp. at 132. In both instances the motion should be granted where there are no material disputed facts and the movant is entitled to the judgment as a matter of law. *See id.*

The pleadings are closed in this case, there is no risk that resolution of this Rule 12(c) motion will delay trial, and resolution of the motion serves the purpose of the Rule. This consolidated case is in its early stages. Boehringer's answer to the last counterclaim was filed June 30, 2016. *See* Docket No. 324.[16] Defendants served preliminary invalidity contentions in January, 2016, and noninfringement contentions in April, 2016. Boehringer served its initial infringement contentions as recently as May 13, 2016. Most importantly, the trial is not scheduled until June 4, 2018 --nearly two years from now. Therefore, the motion is "early enough not to delay trial." Further, granting Defendants' motion would clearly "save time and expense" and pare down this multi-patent case. Defendants' motion also raises a threshold legal issue. "Judgment on the pleadings is particularly appropriate where, as here, there are no disputed material facts at this early stage of the litigation and a party is entitled to judgment as a

[16] Boehringer's last answer to any defendant's counterclaim involving the '156 patent was filed January 14, 2016. *See* Docket No. 216.

matter of law." *Hoch*, 796 F. Supp. at 132. Thus, the Court should consider the merits of Defendants' motion.

Further, the Court should consider the merits irrespective of its decision whether to grant Defendants' motion for leave to amend their contentions, because failure to do so under the present circumstances would be inconsistent with the Federal Rules of Civil Procedure. To be valid, local rules must be consistent with the Federal Rules. 28 U.S.C. § 2071(a); *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.,* 467 F.3d 1355, 1365 (Fed. Cir. 2006); *Anchorage Assocs. v. V.I. Bd. of Tax Review*, 922 F.2d 168, 174 (3d Cir. 1990) (local rules "must be construed and applied in a manner consistent with the Federal Rules of Civil Procedure"). In *O2 Micro*, the Federal Circuit explained that "[a] local rule need not be directly contradictory to a federal rule to be invalid; a local rule that is inconsistent with the purposes of a federal rule is also invalid." 467 F. 3d at 1365. The court further reasoned that "[i]f a local patent rule required the final identification of infringement and invalidity contentions to occur at the outset of the case, shortly after the pleadings were filed and well before the end of discovery, it might well conflict with the spirit, if not the letter, of the notice pleading and broad discovery regime created by the Federal Rules." *Id*. at 1366. Here, applying local rules to prevent Defendants from seeking resolution of a legal matter on the pleadings --shortly after the case began and nearly two years before trial -- would be inconsistent with both the explicit text of Rule 12(c) as well as its purpose to save time and expense when material facts are not in dispute. It would also effectively be requiring "the final identification" of invalidity contentions "at the outset of the case, shortly after the pleadings were filed" and well before trial and would conflict with "the spirit, if not the letter," of the Federal Rules.

Moreover, refusing to consider Defendants' motion because the § 101 defense was not asserted in the original contentions would also be inconsistent with Rule 12 and public policy because the Rule is designed to address threshold legal issues such as patent validity. There is no question that Defendants could have raised this issue in a Rule 12(b)(6) motion, without notice to Boehringer, prior to ever serving invalidity contentions in the first instance. Rule 12(h), which addresses the waiver and preservation of certain defenses including the "failure to state a claim upon which relief can be granted" under 12(b)(6), makes clear that this latter defense may be raised "by a motion under Rule 12(c)" or "at trial." Fed. R. Civ. P. 12(h)(2)(B) and (C). It therefore makes little sense to deny Defendants the right to assert a threshold legal defense under Rule 12(c) that the rules explicitly permit them to bring under Rule 12(b)(6) without *ever* having given Plaintiffs notice of the defense in any event. That is effectively one reason why the court in *Mobile Telecommunications Technologies, LLC v. United Parcel Service, Inc.* decided to address a defendant's Rule 12(c) motion raising a § 101 defense despite the fact that the defendant had not raised the issue in its contentions. *See* --- F. Supp. 3d ---, No. 12-3222, 2016 WL 1171191 at *8 (N.D. Ga. Mar. 24, 2016). As the court explained, it "could have reached" the legal issue presented by the defendant's motion "before discovery even began" and thus there was no prejudicial effect on the plaintiff despite the fact that the disclosure of the defense was otherwise untimely. *Id.* The court noted that "this matter was likely to be heard no matter what, because validity is fundamental" to the plaintiff's ability to recover at trial. *Id.* Likewise, the Third Circuit has observed that "one of the basic objectives of the federal rules [is] the determination of cases on their merits." *Abbott Labs. v. Lupin Ltd.,* No. 09-152, 2011 WL 1897322, at *5 (D. Del. May 19, 2011) (citing *Prof'l Cleaning & Innovation Building Servs., Inc. v. Kennedy Funding, Inc.,* 245 Fed. App'x 161, 165 (3d Cir. 2007) (internal quotations omitted)). This need to resolve cases

on the merits "is particularly true with respect to the validity of patents" because the Supreme Court has emphasized that "public interest favor[s] the judicial testing of patent validity[.]" *Abbott Labs.,* 2011 WL 1897322, at *5 (citing *U.S. v. Glaxo Group Ltd.,* 410 U.S. 52, 69 (1973) (internal quotations omitted)). This is especially true in a Hatch-Waxman case where Boehringer seeks to extend its monopoly on linagliptin other DPP-4 inhibitors well beyond the expiration of the linagliptin compound patent, thereby depriving American consumers of access to affordable generic drugs in contravention of Congress's goal "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).[17]

Here, Defendants raise a threshold legal issue relating to patent validity, the pleadings have only recently closed, trial is nearly two years away, there is no unfair prejudice to Boehringer, the Federal Rules explicitly state that Defendants have not waived threshold legal defenses, and the courts have recognized that questions of patent validity-- particularly those involving pharmaceuticals --raise important public policy issues that should be addressed on the merits. Under these circumstances the Court should consider the merits of Defendants' Rule 12(c) motion --independent of its decision on Defendants' motion for leave to amend their invalidity contentions. Failing to address Defendants' Rule 12(c) motion based on the supposed

[17] *But cf. Good Technology Corp. v. Mobileiron, Inc.,* No. 12-5826, 2015 WL 3866019 (N.D. Cal. May 4, 2015) and *Radware, Ltd. v. F5 Networks, Inc.,* ---F. Supp.3d ---, No. 13-2024, 2015 WL 7960004 (N.D. Cal. Dec. 4, 2015), two Northern District of California cases in which the court declined to consider a Rule 12(c) motion based on § 101 because the defendant had not amended its contentions to include this defense as required by the local rules. In those cases, however, the court did not consider the argument that application of the local rules was inconsistent with the Federal Rules. Furthermore, in the one case where the timing of the motion was addressed, unlike here the defendant had waited a year and a half to raise the issue in the first instance. *See Radware*, 2015 WL 7960004 at *3 - *4. Similarly, in *O2 Micro* the Federal Circuit affirmed the district court's application of the Northern District of California's local patent rules, but that case involved the timing of factual issues raised during discovery and a defendant who changed its invalidity contentions involving differing expert opinions during expert discovery. *See* 467 F.3d at 1356-57, 1366-68. This case involves no such considerations.

lack of good cause to amend invalidity contentions under the local rules would inappropriately conflate the local rules for contentions with the Federal Rules for judgment on the pleadings. It would elevate form over substance and would be inconsistent with the Federal Rules.

CONCLUSION

The claims of the '156 patent cover nothing more than observed pharmacokinetic properties of some DPP-4 inhibitors such as linagliptin and/or the known implications of recognizing them. There is nothing additionally inventive about the claims. The use of DPP-4 inhibitors including linagliptin to treat diabetes was conventional, the knowledge that renal insufficiency was common in diabetics was conventional, the ability to measure renal function was conventional, the use of DPP-4 inhibitors to treat diabetics with renal insufficiency was conventional, and the knowledge that metformin should be avoided in those with renal insufficiency was also conventional. The '156 patent inappropriately attempts to claim laws of nature and preempt research and the use of known antidiabetic drugs in known ways for known conditions. The specification makes clear that the claims do not recite patentable subject matter. No further information is needed and addressing this issue now will save time and expense in this multi-patent case. The claims are invalid under § 101. Defendants respectfully request the Court to enter judgment accordingly and dismiss the '156 patent from the case.

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Respectfully submitted,

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